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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/369,016	08/05/1999	SEAN FARMER	GANEDEN-04(1	6222

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 11/05/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/369,016

Applicant(s)
Farmer

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 7, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-59 and 61-71 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-59 and 61-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The amendment filed 10/7/02 is acknowledged. Claims 51-59 and 61-71 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 51-54 and 61-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51-59 and 61-71 are vague and indefinite in the recitation of "supplementary" with respect to the enzymes included in the composition, even when reading the claim in light of the specification. It is apparent that the term is used as providing a "supplement", and appears redundant in this context.

In this regard, Applicants allege in the instant Response that "a supplementary dietary lactase" is a "lactase in an amount that exceeds that associated with bacterial production of the enzyme". However, this definition is not found in or borne out by the present written disclosure. Therefore, applicants indication that "the amounts of lactase required by the claims are supplemental to any lactase produced by the isolated *B. coagulans*" is incorrect (Response, page 6, paragraph 1).

Claims 65 and 66 are vague and indefinite in the recitation of a suppository in the form of a "dried cell mass" or stabilized "gel", "paste" or "liquid suspension". It is unclear what is intended in this context.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-56, 58-59, 61-64, and 67-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hata taken with Paul and Hansen and further taken with Long and ATCC Catalogue of Bacteria.

Hata teach a process of providing a mammal with nutrients by orally administering yogurt composition containing *Bacillus coagulans*. The strain of Hata is also known as *L. thermophilus* (See, e.g., col. 2, lines 28-35). The natural effect of consuming *Bacillus coagulans* containing compositions is to increase bioavailability of nutrients. The reference differs from the claimed invention in that the yogurt does not explicitly contain a fructo-oligosaccharide and gluconate or citrate. However, at least citrate is known to be frequently added to yogurt compositions. In addition, Paul discloses compositions containing lactic acid bacteria and fructo-oligosaccharides, with the indication that fructo-oligosaccharides are a valuable addition to lactic acid producing bacterial compositions because of their contents of soluble fiber, an additive known to be beneficial to general health. In addition the reference teaches the combination of a lactic-acid producing bacterium, a fructo-oligosaccharide and sodium gluconate. (See, e.g., col. 15, lines 10-20). Moreover, Hansen *et al.* disclose the addition of various citrates and gluconates to yogurt, including calcium gluconate and/or calcium citrate for the purpose of adding valuable bioavailable nutrients (See, e.g., col. 4, lines 45) as well as the addition of fibers, which suggests the addition of fructo-oligosaccharides.

The references appear to differ from the claimed invention in that the compositions disclosed do not explicitly recite the presence of lactase. However, Long *et al.* adequately demonstrates that the presence of lactase in *B. coagulans* is inherent in the species. See, e.g., Long *et al.*, col. 4, lines 6-39. Accordingly, one of ordinary skill in the art would have been motivated to administer *B. coagulans* in milk-containing compositions, such as yogurt, with a reasonable expectation of providing compositions which are easily digestible in view of the availability of the lactose degrading enzyme lactase produced by this microorganism.

In addition, ATCC Catalogue adequately demonstrates that *B. coagulans* ATCC 31284, the strains grown by applicants and used in the present invention was previously classified as *Lactobacillus sporogenes* (See, e.g., page 45; Specification, page 16). Therefore, there is a clear nexus between the reference taught compositions and the instant invention.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose as noted *supra*. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention is predicated on an unexpected

result, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions and ingredients where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the composition and process of administering nutrients and disclosed by Hata using strains of *Lactobacillus* now reclassified as *B. coagulans* or other *B. coagulans* strains by supplementing the milk-containing composition yogurt, for example, with citrate or gluconate compounds as taught by Paul and Hansen for the expected benefit of increasing the digestibility and the nutritional content of food and thus maximize the health benefits to the mammal being fed.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

As noted in the rejection under 35 U.S.C §112, second paragraph, Applicants allegation in the instant Response that "a supplementary dietary lactase" is a "lactase in an amount that exceeds that associated with bacterial production of the enzyme" is a definition not found in or borne out by the present written disclosure. Therefore, applicants indication that "the amounts of lactase required by the claims are supplemental to any lactase produced by the isolated *B. coagulans*" is incorrect (Response, page 6, paragraph 1). In other words, there is nothing in the as-filed specification to suggest that "supplementary" should be equated with "exogenous" as appears to be argued.

With respect to arguments directed to the use of the transitional phrase "consisting essentially of", it is noted that this phrase limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants'

specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

Inasmuch as the ancillary ingredients, such as dried milk do not appear to materially affect the basic and novel characteristics of the claimed methods and composition, and because Applicants have not provided probative evidence to demonstrate unexpected properties for the claimed compositions, the rejection is deemed proper and it is adhered to.

Claims 57, and 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hata taken with Reid, of record.

The Hata reference is discussed above.

The claims differ from the claimed invention in that *B. coagulans* is administered as a suppository. However, Reid adequately demonstrates that the administration to a mammal of a suppository comprising a lactic acid producing bacteria is old and well known in the art. The effect of increasing bioavailability of nutrients is an intrinsic property of the composition.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Reid *et al.* of administering bacteria as formulated as suppositories by administering strains of *Lactobacillus* now reclassified as *B.*

coagulans or other *B. coagulans* strains as taught by Hata for the expected benefit of aiding digestion and thus maximize the health benefits to the mammal being treated.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

No claim is allowed.

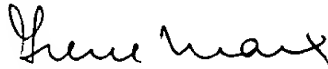
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx
Primary Examiner
Art Unit 1651